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MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

JULY 25, 2005.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany S. 1420]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1420) to amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY

The purpose of S. 1420, the "Medical Device User Fee Stabilization Act of 2005," is to ensure that the medical device user fee program at the Food and Drug Administration (FDA) continues in fis-

cal years 2006 and 2007; to moderate the rate of increase of device user fees and lessen the burden of user fees on smaller device companies; and to ensure the marking of reprocessed single-use devices so that users can more easily identify whether the devices have been reprocessed and who has reprocessed them.

In particular, the bill amends provisions in current law that require that a certain sum be appropriated for devices at the FDA over the course of fiscal years 2003 to 2006. Without such a change, FDA would be unable to collect device user fees in fiscal year 2006 and 2007. The bill modifies the way user fees are set in current law to establish user fees in fiscal year 2006 at 8.5 percent more than 2005 user fees and user fees in 2007 at 8.5 percent more than 2006 fees. The bill also increases the revenue threshold below which a device company is considered to be a small business and therefore eligible for reduced user fees from $30 million to $100 million with respect to most marketing applications. Finally, the bill amends current law to clarify that in nearly all instances, the reprocessor of a reprocessed single-use medical device must be identified through markings on the device or an attachment thereto.

II. Background and Need for Legislation

On October 26, 2002, the Medical Device User Fee and Modernization Act (MDUFMA) (P.L. 107–250, 116 Stat. 1616) was signed into law. MDUFMA amended the Federal Food, Drug and Cosmetic Act (FFDCA) to authorize FDA to collect user fees from manufacturers who submit certain applications to market medical devices. The premise behind initiating a user fee program for medical devices was to provide for more timely and predictable review of medical device applications, as well as to make the necessary infrastructure investments required to conduct review of increasingly complex medical device applications in a timely and predictable fashion. In exchange for this authority, FDA has committed to pursue a comprehensive set of performance goals and commitments. MDUFMA also included enhanced regulatory requirements for reprocessed single-use devices.

The FFDCA, as amended by MDUFMA, authorizes FDA to collect user fees for certain medical device applications in fiscal year 2006 and fiscal year 2007 only if certain conditions are met. However, MDUFMA specifies that for fiscal year 2006, fees may not be assessed if the total amounts appropriated for fiscal year 2003 through fiscal year 2005 for FDA's device and radiological health program are less than levels specified in MDUFMA (section 738(g)(1)(C) of the FFDCA).

Appropriations for fiscal year 2003 through fiscal year 2005 for FDA's device and radiological health program were below the amount specified in MDUFMA. This amendment modifies those minimum appropriation levels for fiscal years 2003 and 2004 to allow FDA to continue to collect user fees until October 1, 2007, thus preventing the program's premature termination on September 30, 2005.

The committee believes it is important to provide industry with predictable annual increases in application fees. Since the inception of MDUFMA, user fees for certain application types have increased much faster than had been expected. These increases have imposed unanticipated costs on companies in the medical technology indus-

try. To address these concerns, this amendment will set specific fee increases in fiscal year 2006 and fiscal year 2007 until MDUFMA's authorization expires on October 1, 2007.

Under MDUFMA, device user fees were structured to provide lower fees for companies with revenues of less than $30 million a year. In reviewing the impact of MDUFMA, the committee is concerned that this fee structure imposes barriers to marketing a new device on small device companies with annual revenues above $30 million.

User fees make possible FDA's investments in information technology infrastructure and human capital, more comprehensive training for device reviewers, greater use of experts in academia and the private sector, enhanced project management, increased guidance development, expanded participation in globalization and standards setting activities, and increased interaction with industry both before and during the application review process. As medical device applications become progressively more complex, this investment will become ever more necessary to keep up with performance goals that FDA has thus far been successful in meeting—performance goals intended to speed promising new technologies to patients. Keeping the device review program on sound financial footing is essential to ensure timely and predictable review of medical device applications. The committee believes that FDA has made good progress in implementing MDUFMA and is making satisfactory progress towards achieving the performance goals set under MDUFMA.

Finally, reprocessed single-use devices are not generally marked to identify their reprocessor. Adverse events associated with a reprocessed device may therefore be misattributed to the original manufacturer, and not to the reprocessor. In addition, when reporting adverse events, health care providers may mistakenly believe that the device is a new, unused product from the original manufacturer of the device, and not from a reprocessor. In 2002, the provisions in Section 301 of MDUFMA, which were intended to lead to the marking of reprocessed single-use medical devices, created concerns regarding both the feasibility and timing of implementation.

III. Legislative History and Committee Action

On July 18, 2005, Senators Enzi, Kennedy, Burr, DeWine, Mikulski, Dodd and Murray introduced S. 1420, the "Medical Device User Fee Stabilization Act of 2005." On July 20, 2005, the committee held an executive session to consider S. 1420. After accepting an amendment in the nature of a substitute offered by Senator Enzi, and adding Senator Hatch as a cosponsor, the committee approved S. 1420, as amended, by unanimous voice vote.

IV. Explanation of Bill and Committee Views

USER FEES

Whether used to diagnose a disease or condition or to treat it, medical devices are used daily to improve the quality of care and quality of life of patients all around the country. Device manufacturers continually improve their products to improve safety or ef-

fectiveness, and totally new devices offer breakthroughs to patients that will change how diseases are diagnosed or treated.

The committee believes it is imperative that FDA review medical devices promptly and quickly to speed both incremental and breakthrough innovations to patients. The medical device user fee program has already resulted in improvements in the speed with which FDA reviews medical device submissions, including pre-market applications for Class III devices and supplements to those applications under section 515 of the FFDCA, and pre-market notifications, or 510(k)s, under section 510(k) of the FFDCA.

The committee believes the device user fee program offers great promise for improving the speed of device reviews, and that the program cannot be allowed to terminate on September 30, 2005. For this reason, S. 1420 eliminates the "trigger" provision that would prohibit FDA from collecting user fees in fiscal years 2006 and 2007 because appropriations to FDA for devices did not meet specified amounts in fiscal years 2003 and 2004. However, a comprehensive review of all aspects of MDUFMA is warranted prior to its reauthorization in 2007 to ensure that the program is operating as intended.

In addition, because of concerns about the rate at which device user fees have been growing over the past few years, S. 1420 locks in a rate of increase for individual user fees of 8.5 percent in both fiscal years 2006 and 2007. The user fee for a pre-market approval application in fiscal year 2005 is $239,237. Under S. 1420, this fee will increase to $259,600 in 2006 and to $281,600 in 2007. The reduced pre-market approval application fee for small businesses is $90,910 in fiscal year 2005, and will increase to $98,700 in 2006 and $107,000 in 2007. This fixed 8.5 percent rate of increase in fees requires that the "guaranteed" fee revenue amounts to FDA, as well as the inflation, workload, and compensating adjustments in current law, be eliminated.

Small businesses will receive additional financial relief because S. 1420 changes the definition of "small business" for the purpose of paying a reduced user fee (but not for receiving a first-time user fee waiver) from $30 million in annual gross receipts or sales to $100 million. The committee notes that setting the small business threshold at $100 million is estimated to result in 723 firms qualifying, versus 570 firms at the current level of $30 million. This estimate is based on data suggesting that an additional 3.8 percent of device firms qualify as small businesses for every $10 million increase in the threshold. FDA will report to Congress on the number of different applications and notifications, and the total amount of fees paid for each type, from businesses with gross receipts or sales at or below $100 million for fiscal years 2006 and 2007.

The committee expects that the 8.5 percent increase in fees will result in an average annual increase to FDA of device user fee revenues of 6 percent, and that this level of revenues is sufficient to keep the device review program running at a pace that will maintain the speed of reviews without compromising safety. To provide FDA with a measure of financial security should fee revenues fall short of current projections, S. 1420 permits FDA to use unobligated carryover balances of user fees collected in previous years to supplement user fee collections in fiscal years 2006 and 2007, provided the FDA maintains a balance of such carryover funds to

allow for operations in the first month of fiscal year 2008. In addition, the agency must send a notice to the Senate Committee on Health, Education, Labor, and Pensions, the House Committee on Energy and Commerce, and both Committees on Appropriations at least 14 days prior to using these funds. To ensure that funds are not directed away from device safety activities, FDA must certify that the amounts spent by the agency for salaries and expenses to perform device-related activities not pertaining to the review of applications are no less than the amounts spent on those functions in fiscal year 2002 multiplied by the compounded rate of inflation.

The committee recognizes that eliminating the adjustment factors in the user fee calculations puts the full risk of any shortfalls in anticipated fees on the FDA. While the potential use of the unobligated carryover funds protects the agency against adverse consequences that may occur during the 2-year period covered by the bill, the committee recognizes that adjustments may need to be made in the program in the future to assure greater stability in the revenues received from user fees.

The committee notes that Congress met the statutory appropriations figure for fiscal year 2005 after a full request for funding in the budget for that year. The 2006 budget request included the full amount needed for 2006, and legislation appropriating the full amount for the device user fee program for fiscal year 2006 has been reported out of both the House and Senate Appropriations Committees. The committee notes further the commitment letter from the Office of Management and Budget regarding the Administration's intention that the fiscal year 2006 and 2007 budget requests will include the full amount authorized for devices at FDA under the user fee program.

REPROCESSING OF SINGLE-USE DEVICES

Original manufacturers typically label or imprint the company's name and logos directly on their medical devices. This branding, together with product familiarity, allows physicians, hospital staff, and patients to associate a particular device with a particular original manufacturer, and is especially important in the event of a recall, warning, patient injury, or product malfunction. The committee believes it is essential to require the specific identification of reprocessed versions of single-use devices to ensure that physicians, nurses, users, and hospital administrators know that a device they have used was reprocessed.

In 2002, section 301 of MDUFMA added a new subsection (u) to section 502 of the FFDCA to require devices (both new and reprocessed) to prominently and conspicuously bear the name of the manufacturer, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying the manufacturer. Under this provision, FDA could waive this requirement if compliance is not feasible or compromises the reasonable assurance of safety or effectiveness of the device.

The committee is aware that FDA chose to exercise its enforcement discretion with respect to section 502(u) of the FFDCA, rather than implement it. There were significant and legitimate concerns about the provision as initially passed in MDUFMA—it applied to all devices, and it included a potentially burdensome waiver provision that could have consumed resources at FDA. Congress

subsequently ratified FDA's concerns and delayed the effective date of section 301 of MDUFMA by 18 months, to October 26, 2005, in the Medical Device Technical Corrections Act (P.L. 108–214, 118 Stat. 575).

Section 519 of the FFDCA, and FDA's Medical Device Reporting (MDR) regulations, require manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA or the manufacturer. This reporting requirement is the cornerstone of FDA's post-marketing surveillance system for medical devices, and it cannot work as intended unless health care providers, original manufacturers, device reprocessors, and FDA can readily and accurately identify when a single-use device has been reprocessed. However, unless marked, once a medical device is removed from its packaging, health care providers may not be able to determine whether it is an original device or one that has been reprocessed. Moreover, there is evidence to indicate that the lack of specific labeling to identify reprocessed devices may lead to inadequate reporting of patient injuries and product malfunctions involving reprocessed single-use devices, particularly where a reprocessed device bears only the mark of the original manufacturer. This undermines the purpose and effectiveness of section 519 of the FFDCA and FDA's MDR regulations, leaving FDA with a less accurate picture of the post-market safety and effectiveness of these devices.

In 2000, the Government Accounting Office (GAO) conducted an audit of the MDR system as it relates to reprocessed single-use devices. GAO concluded that the current surveillance systems for medical errors and adverse events do not detect all infections and injuries associated with the use of medical devices. See GAO Report: Single Use Medical Devices (June 2000). Section 502(u), as redrafted in S. 1420, is designed to address this concern as it relates to reprocessed single-use devices, and can only be effective if the provision is promptly implemented by reprocessors and strictly enforced by FDA.

The committee has carefully considered the concerns about section 502(u) as originally adopted and has amended it to provide a far more narrow provision that should be essentially self-effectuating. Section 502(u) now focuses on reprocessed single-use devices. Any single-use device reprocessed from an original device that the original manufacturer has prominently and conspicuously marked (which may be accomplished through marking an attachment to the device) with its name, a generally recognized abbreviation of its name, or a unique and generally recognized symbol for it, must be prominently and conspicuously marked (which may be accomplished through marking an attachment to the device) with the reprocessor's name, a generally recognized abbreviation of its name, or a unique and generally recognized symbol for it.

There is no possibility of a waiver of the 502(u) requirements under the statute as amended by S. 1420, and FDA will not be confronted with a resource-intensive waiver process. Moreover, the committee is convinced that reprocessors will be able to comply completely with the requirements of section 502(u): if the original manufacturer is able to mark its product, the reprocessor should be able to as well, especially since section 502(u) permits the marking of an attachment to the device. When the original manufacturer

has not marked its device, the reprocessor still must identify the device as reprocessed, but may do so through the use of a technology that some already use, a detachable label identifying the reprocessor that is placed on the package containing the device. Where the original manufacturer has marked its product in such a way that there is little or no usable space for a reprocessor to prominently and conspicuously mark the device, the reprocessor may satisfy section 502(u) through the use of an attachment to the device.

The committee therefore believes there is no reason for FDA to delay implementation of section 502(u) or to elect to exercise enforcement discretion in the face of non-compliance with its requirements. Although section 502(u) will first become effective 12 months after the legislation is enacted, the committee believes that it is clear how this section applies to the vast majority of reprocessed devices, and the committee expects reprocessors to implement its requirements as soon as possible for the devices they reprocess, in the best interest of post-market surveillance and the public health.

With respect to the marking requirement on single-use devices that the original manufacturer has not marked, the committee understands that some reprocessors should be able to implement this provision immediately. With respect to devices the original manufacturer has marked, the committee expects reprocessors to begin marking at least some of the devices they reprocess as soon as is feasible and to work expeditiously to mark all other reprocessed devices well before the 12-month deadline but in no case later than that deadline, in the best interest of post-market surveillance and the public health.

The committee wishes to emphasize that section 502(u)(2) of the FFDCA, which permits the identification of reprocessors through use of a detachable label on the packaging rather than directly on the device or an attachment thereto, applies only when the original manufacturer has not prominently and conspicuously marked its device. This package label is intended to be placed in the medical record of the patient on whom the device is then used. The committee recognizes that a detachable label facilitates reporting of adverse events under section 519(b) of the FFDCA only if the label is actually placed in the patient's medical record. The FDA should work with device user facilities, including hospitals, to assure that detachable labels are used as intended so that facilities can accurately identify the manufacturer of a single-use device implicated in an adverse event.

Although the committee encourages the use of these detachable labels on all reprocessed devices, the use of such a detachable label on a reprocessed single-use device that is prominently and conspicuously marked by the original manufacturer is not a legitimate substitute for the requirement of section 502(u)(1) that the reprocessor directly mark the reprocessed device or an attachment to it. In order to avoid erroneous identification of the original manufacturer as the source of a reprocessed device and to ensure that the MDR system provides FDA with the information it needs with respect to reprocessed devices to adequately protect patients, the identification of the reprocessor by means of a detachable package label is strictly limited to those circumstances where the device

itself, or an attachment thereto, does not prominently and conspicuously reflect the identity of the original manufacturer.

The legislation requires FDA to issue a guidance document to identify circumstances under which the original device is not considered to be "prominently and conspicuously" marked with the name, a generally recognized abbreviation of the name, or a unique and generally recognized symbol for the original manufacturer. Section 502(c) of the FFDCA requires that information that must appear on the label or in the labeling of a device must appear prominently and conspicuously and in such terms "as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The committee believes that this definition will be instructive in determining how section 502(u) applies, but it notes that there are aspects of device marking that are not parallel to labeling, and intends that those aspects will be addressed by the guidance document.

The committee believes there are only two circumstances in which an original device would not be considered to be prominently and conspicuously marked: devices that the original manufacturer has not marked at all, and devices on which the mark is very small or the device itself is very small. It is clear when a device has not been marked by the original manufacturer at all, and thus the committee does not expect the FDA to address those devices in the guidance. The committee believes it is unlikely that original manufacturers would by choice mark a product without making its mark prominent and conspicuous. For a very small device, by contrast, a mark on the device itself—in contrast to a mark on an attachment to the device—would not likely be prominent and conspicuous. The mark itself would of necessity be extremely small. It is these devices that the FDA should address in the guidance.

Section 519 of the FFDCA, and FDA's Medical Device Reporting (MDR) regulations, require manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA or the manufacturer. The committee believes that the requirements of section 502(u), as amended, will operate to improve this post-market surveillance system, and thus patient safety.

V. Cost Estimate

Due to time constraints the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record at a later time.

VI. Application of Law to the Legislative Branch

The committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

VII. Regulatory Impact Statement

Pursuant to the requirements of paragraph 11(b) of Rule XXVI of the Standing Rules of the Senate, the committee has determined that the bill will not have a significant regulatory impact.

VIII. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides the short title of the bill, the Medical Device User Fee Stabilization Act of 2005.

Section 2. Amendments to the Federal Food, Drug and Cosmetic Act

This section amends section 738 of the FFDCA (Authority to Assess and Use Device Fees), section 103 of MDUFMA, section 502(u) of the FFDCA (Misbranded Devices), and section 301(b) of MDUFMA.

Subsection (a) addresses amendments to the device user fee program authorized in section 738 of the FFDCA. Subsection (a)(1) eliminates the statutory fee revenue targets for device user fees in fiscal years 2006 and 2007 in section 738(b).

Subsection (a)(2) eliminates the inflationary, workload, compensating, and final year adjustments previously used in annual fee-setting calculations, as provided for in section 738(c). Subsection (a)(2) also sets the pre-market application user fee at $259,600 for fiscal year 2006 and $281,600 for fiscal year 2007, which is an 8.5 percent increase each year (fees for other device submissions are then determined as a percentage of the pre-market application fee, as provided generally in section 738(a)(2)(A)). Finally, subsection (a)(2) also amends section 738(c) to permit FDA to use up to two-thirds of fees carried over from previous years to supplement fee revenues in fiscal years 2006 and 2007. FDA must notify Congress if it intends to use these carryover balances.

Subsection (a)(3) amends section 738(d) to clarify that the small business threshold for the purposes of a first-time waiver of the fee on a pre-market approval application or a pre-market report remains at $30 million, as under current law. It raises the small business threshold from $30 million to $100 million for the purposes of fee reductions on all other applications, reports, and supplements. Subsection (a)(3) also eliminates the ability of the FDA to reset this new small business threshold if user fee revenues are reduced by 16 percent because of the small business fee reduction. Subsection (a)(4) amends section 738(e) to raise the small business threshold from $30 million to $100 million for the purposes of fee reductions on pre-market notifications.

Subsection (a)(5) amends section 738(g) to eliminate the "trigger" requirement of additional appropriations in the fiscal years 2003 and 2004 for FDA to be able to collect user fees in fiscal year 2006 and 2007. It also builds in a 1 percent tolerance on the appropriations trigger for 2006 and 2007, to cushion against possible across-the-board rescission in the appropriations process for those years, which would lead to accidental termination of the program.

Subsection (a)(6) eliminates the statutory authorization targets for fiscal years 2006 and 2007, and subsection (a)(7) makes a conforming amendment throughout section 738.

Subsection (b) amends section 103 of MDUFMA to require additional information in FDA's medical device user fee program annual reports for fiscal years 2006 and 2007 on the number and types of applications received by the size of small business up to the new small business threshold of $100 million, and to require a certification by the Secretary of Health and Human Services in

the annual report that appropriated funds obligated for other purposes relating to medical devices are not diverted for device review.

Subsection (c)(1) amends section 502(u) of the FFDCA to address the marking and tracking of reprocessed medical devices intended for single-use by the original manufacturer. Section 502(u) as amended requires reprocessors to mark a reprocessed device if the original manufacturer has marked the device. If the original manufacturer does not mark the device, the reprocessor must still mark the device, but has more flexibility in how to mark the device, such as by using a detachable label on the package of the device that is intended to be placed in the medical record of the patient on whom the device is used.

Subsection (c)(2) requires FDA to issue a guidance document no later than 180 days after the act becomes effective to address compliance with section 502(u) in circumstances where an original manufacturer has not marked the original device prominently and conspicuously.

Subsection (d) amends section 301(b) of MDUFMA to make the amendment made by subsection (c)(1) to section 502(u) of the FFDCA effective 12 months after the date of enactment of the act, or 12 months after the original manufacturer has first marked its device, if that is later.

IX. ADDITIONAL VIEWS

ADDITIONAL VIEWS OF SENATOR HATCH

When Congress passed the Medical Device User Fee and Modernization Act (MDUFMA) in 2002, it made several important findings, noting that prompt approval and clearance of safe and effective devices is critical to the improvement of public health and that public health is served by augmenting the funds available to the Food and Drug Administration (FDA) for the review of devices and assurance of their safety and effectiveness. A key element of MDUFMA was that the FDA would be able to meet performance goals for device review with the additional resources provided by the new law.

There is no question that FDA review times for medical devices have improved in some areas since the law's enactment. For example, according to information provided by the FDA, review times for 510(k)s have improved with the average percentage of final decisions made within 90 FDA review days increasing from 77 percent in fiscal year 2002 to 84 percent in fiscal year 2004. During that same period, preliminary data show that FDA's time to approval for original PMAs also improved. The average FDA time to PMA approval decreased from 260 days in fiscal year 2002 to fewer than 220 days in fiscal year 2004.

Even so, that progress is not as dramatic as many had hoped when the user fee bill was originally considered. And, relying on statistical averages masks a significant number of outliers whose review times fall nowhere near the average. Indeed, FDA's ability to review products in a timely fashion still falls far short of the optimum. That inability to meet deadlines cannot be solely attributed to resources.

The Federal Government has an important role in assuring the safety and efficacy of products such as medical devices in order to fulfill its mandate of protecting the public health. Not as often noted, however, is the equally important role of government in fostering the incredible innovation that has made America's medical device industry world-renowned.

Indeed, many of us have been concerned that Food and Drug Administration (FDA) user fees can serve as a tax on innovation, hindering the development of life-sustaining products that do so much to help our citizens lead healthier, happier lives. This is especially true for smaller device companies, who recognize user fees as a substantial barrier to entry. That is why this bill's provision to set a small business threshold of $100 million is particularly important.

Despite concerns about the equity of user fees, we recognize that without the resources provided through user fees, the FDA's tightly-constrained budget does not allow the progress on product re-

views that is necessary to maintain the government's critical review function. The questions then become how best to construct those fees so that they are fair, promote innovation, and improve productivity at the agency.

Those questions will not be answered through enactment of this legislation, but they must be answered nonetheless. I look forward to working with Chairman Enzi, Ranking Democrat Kennedy and other members of the committee to develop ways to implement more measurable performance goals and increase the agency's productivity when the law is reauthorized in 2007. In the interim, the Medical Device User Fee Stabilization Act (MDUFSA) is an important measure that is worthy of support.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.— * * *

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (d) and (e), each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under [subsection (c)(5)] *subsection (c)(1)* for the fiscal year involved in accordance with the following:

(i) * * *

* * * * * * *

(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (e), (g), and (h), the fees under subsection (a) shall be established to generate the following revenue amounts: $25,125,000 in fiscal year 2003; $27,255,000 in fiscal year 2004; *and* $29,785,000 in fiscal year [2005; $32,615,000 in fiscal year 2006, and $35,000,000 in fiscal year 2007] *2005*. If legislation is enacted after the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.

(c) [ADJUSTMENTS.—] *Annual Fee Setting.*—

[(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

[(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30

preceding the fiscal year for which fees are being established, or

[(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

[(2) WORKLOAD ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year to reflect changes in the workload of the Secretary for the process for the review of device applications. With respect to such adjustment:

[(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of premarket applications, investigational new device applications, premarket reports, supplements, and premarket notification submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

[(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

[(3) COMPENSATING ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year, if necessary, to reflect the cumulative amount by which collections for previous fiscal years, beginning with fiscal year 2003, fee below the cumulative revenue amounts for such fiscal years specified in subsection (b), adjusted for such fiscal years for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2).

[(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fees and fee revenues established in subsection (b) if such adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of device applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover user fee balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.]

[(5)] *(1)* [ANNUAL FEE SETTING.—] *IN GENERAL.*—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, [establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustment provided under this subsection and subsection (e)(2)(C)(ii), except that the fees] *publish in the Federal Register fees under subsection (a). The fees* established for fiscal year [2003] *2006* shall be based on a premarket application fee of [$154,000.] *$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600.*

[(6)] *(2)* LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

(3) SUPPLEMENT.—

(A) IN GENERAL.—For fiscal years 2006 and 2007, the Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of fiscal year 2008.

(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. *For the purposes of this paragraph, the term "small business" means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.* In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—

[(i) IN GENERAL.—] For purposes of this [subsection,] *paragraph,* the term "small business" means an entity that reported [$30,000,000] *$100,000,000* or less of gross receipts or sales in its most recent Fed-

eral income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

[(ii) ADJUSTMENT.—The Secretary may adjust the $30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.]

(B) * * *

(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under [subsection (c)(5)] *subsection (c)(1)* may be paid at a reduced rate of 38 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.

* * * * * * *

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—* * *

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—For purposes of this subsection, the term "small business" means an entity that reported [$30,000,000] *$100,000,000* or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

(B) * * *

(C) REDUCED FEES.—

(i) IN GENERAL.—For fiscal year 2004 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 80 percent of the fee that applies under subsection (a)(2)(A)(vii), as adjusted under clause (ii) and as established under [subsection (c)(5)] *subsection (c)(1)*.

(ii) ADJUSTMENT PER FEE REVENUE AMOUNT.—For fiscal year 2004 and each subsequent fiscal year, the Secretary, in setting the revenue amount under [subsection (c)(5)] *subsection (c)(1)* for premarket notification submissions, shall determine the revenue amount that would apply if all such submissions for the fiscal year involved paid a fee equal to 1.42 percent of the amount that applies under subsection (a)(2)(A)(i) for premarket applications, and shall adjust the fee under subsection (a)(2)(A)(vii) for premarket notification submissions such that the reduced fees collected under clause (i) of this subparagraph, when added to fees for

such submissions that are not paid at the reduced rate, will equal such revenue amount for the fiscal year.

* * * * * * *

(g) CONDITIONS.—

(1) PERFORMANCE GOALS THROUGH FISCAL YEAR 2005; TERMINATION OF PROGRAM AFTER FISCAL YEAR 2005.—* * *

(A)(i) * * *

* * * * * * *

(B)[(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

[(I) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

[(II) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

[(III) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.] *(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than $205,720,000 multiplied by the adjustment factor applicable to the fiscal year.*

[(ii) For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:] *(ii) For fiscal year 2005, if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is more than 1 percent less than the amount that applies under clause (i), the following applies:*

* * * * * * *

(C) For fiscal year 2006, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if the total of the amounts so appropriated for fiscal years [2003 through] *2005 and* 2006, excluding the amount of fees appropriated for such fiscal years, is *more than 1 percent* less than the sum of—

(i) * * *

(ii) an amount equal to the [sum] *amount* that applies for purposes of subparagraph (B)(i).

(D) For fiscal year 2007, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(i) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is *more than 1 percent* less than $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2007; or

* * * * * * *

(h) CREDITING AND AVAILABILITY OF FEES.—
(1) IN GENERAL.—* * *

* * * * * * *

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—
(A) $25,125,000 for fiscal year 2003;
(B) $27,225,000 for fiscal year 2004;
(C) $29,785,000 for fiscal year 2005[;]*; and*
[(D) $32,615,000 for fiscal year 2006; and
[(E) $35,000,000 for fiscal year 2007,
as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application fees.] *(D) such sums as may be necessary for each of fiscal years 2006 and 2007.*

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—
(a) * * *

* * * * * * *

[(u) If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.]

(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

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MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

SEC. 103. ANNUAL REPORTS.

[Beginning with] *(a)* IN GENERAL.—*Beginning with* fiscal year 2003, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report concerning—

(1) * * *

* * * * * * *

(b) ADDITIONAL INFORMATION.—For fiscal years 2006 and 2007, the report described under subsection (a)(2) shall include—

(1) information on the number of different types of applications and notifications, and the total amount of fees paid for each such type of application or notification, from businesses with gross receipts or sales from $0 to $100,000,000, with such businesses categorized in $10,000,000 intervals; and

(2) a certification by the Secretary that the amounts appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year and obligated by the Secretary for the performance of any function relating to devices that is not for the process for the review of device applications, as defined in paragraph (5) of section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are not less than such amounts for fiscal year 2002 multiplied by the adjustment factor, as defined in paragraph (7) of such section 737.

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PUBLIC LAW 108–214

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SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107–250.

(a) * * *

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[(c) TITLE III; ADDITIONAL AMENDMENTS—

[(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107–250 (116 Stat. 1616), is amended by striking "18 months" and inserting "38 months".]

(b) EFFECTIVE DATE.—*Section 502(u) of the Federal Food, Drug, and Cosmetic Act (as amended by section 2(c) of the Medical Device User Fee Stabilization Act of 2005)—*

(1) shall be effective—

(A) with respect to devices described under paragraph (1) of such section, 12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005, or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, whichever is later; and

(B) with respect to devices described under paragraph (2) of such section 502(u), 12 months after such date of enactment; and

(2) shall apply only to devices reprocessed and introduced or delivered for introduction in interstate commerce after such applicable effective date.

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